Dräger
MEDICAL

Evita 4 Sat

SpO2 Monitoring Option

Addendum to
Operating Instructions
Evita 4 / Evita 2 dura

xxx

NOTICE

Proprietary Information

This document contains information in which Draeger Medical, Inc. claimed proprietary rights. The information may not be reproduced in whole or in part except as authorized in writing by Draeger. This information is the property of Draeger Medical, Inc., it is provided solely for the use intended.

Repairs/Modifications

Repairs on this device shall be performed only by DraegerService or its Authorized Service Centers. Information about repairs can be obtained from Draeger or Authorized Dealers. Draeger Medical, Inc. will not be responsible for injury to persons or damage to property arising directly or indirectly out of unauthorized repairs or modifications to this device. Furthermore, any unauthorized repairs or modifications void any warranty extended by Draeger.

This document is provided for your information only. It will not be exchanged or updated without request.

Trademarks

The Draeger name and logo are registered trademarks of Dräger.

OXISENSOR, DURASENSOR, AND OXIBAND are trademarks of Nellcor Puritan Bennett Corporation

© Dräger Medical AG & Co. KGaA, 2001

All rights reserved, Subject to modifications

Contents

Important Safety Information READ THIS FIRST..... 4
Operator's Responsibility for Patient Safety..... 4
Limitation of Liability..... 4
Warranty..... 5
Definitions..... 6
General WARNINGS and CAUTIONS..... 6
Precautions During Preparation..... 7
Precautions During Operation..... 7
Precautions During Maintenance..... 7

Intended Use..... 8

Preparation..... 9
Installation..... 9
Sensor selection..... 9
C-Lock ECG synchronization..... 10

Operation With Evita 4..... 11
Measuring SpO_2 11
Displaying the Plethysmogram 11
Setting Alarm Limits 12
Switching Off SpO_2 Monitoring..... 13
Configuring Start Up Defaults for Alarm Limits 13

Operation With Evita 2 dura..... 14
Measuring SpO_2 14
Displaying the Plethysmogram 14
Setting Alarm Limits 15
Switching Off SpO_2 Monitoring..... 15
Configuring Start Up Defaults for Alarm Limits 15

Applying SpO_2-Sensors 17
Tips to Avoid Artifacts 17
Applying the Durasensor DS-100 A 18
Applying the Oxisensor D-25 and D-20 19
Applying the Oxisensor I-20 19
Applying the Oxisensor R-15 20

Troubleshooting 21

Maintenance..... 22
Maintenance Intervals..... 22

Technical Data..... 23

Theory of Operation..... 24
SpO2 Measurement – Measuring Principle..... 24

Ordering Information..... 26

Index..... 28

Important Safety Information

Operator's Responsibility for Patient Safety

For correct and effective use of the product and in order to avoid hazards it is mandatory to carefully read and to observe all portions of this manual.

The design of the intensive care ventilators this device is intended to be used with, accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of the equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Draeger design. This publication excludes references to various hazards which are obvious to a medical professional and operator of respiratory care equipment, to the consequences of misuse of such equipment, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. Draeger Medical, Inc. disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from uses of the product not covered by its intended use or from the combination of this product with other products whether supplied by Draeger or by other manufacturers if such a combination is not endorsed by Draeger Medical, Inc..

The operators of ventilator systems must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. The responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

Limitation of Liability

Draeger Medical, Inc.'s liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon Draeger Medical, Inc.'s Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to Draeger Medical, Inc. and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

THE STATED EXPRESSED WARRANTIES ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR NONINFRINGEMENT.

Draeger Medical, Inc. shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

Warranty

All Draeger products are guaranteed to be free of defects for a period of one year from date of delivery. The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by Draeger Medical, Inc. or its representatives are not covered.
2. Rubber and plastic components and materials are-warranted to be free of defects at time of delivery.
3. Oxygen sensors capsules have a six-month limited warranty from the date of delivery.

Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with Draeger Medical, Inc. holding the option. Draeger Medical, Inc. is not responsible for deterioration, wear, or abuse. In any case, Draeger Medical, Inc. will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

1. Draeger Medical, Inc. or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
2. Defective material or equipment must be returned, shipping prepaid, to Draeger or its authorized representative.
3. Examination by Draeger Medical, Inc. or its authorized representative must confirm that the defect is covered by the terms of this warranty.
4. Notification in writing, of defective material or equipment must be received by Draeger Medical, Inc. or its authorized representative no later than two (2) weeks following expiration of this warranty.

In order to assure complete protection under this warranty, the Customer Registration Card and/or Periodic Manufacturer's Service Record (if applicable) must be returned to Draeger within ten (10) days of receipt of the equipment.

The above is the sole warranty provided by Draeger Medical, Inc. No other warranty expressed or implied is intended. Representatives of Draeger are not authorized to modify the terms of this warranty.

Draeger Medical, Inc., Telford, PA

Definitions

WARNING !

A WARNING statement refers to conditions with a possibility of personal injury if disregarded.

CAUTION !

A CAUTION statement designates the possibility of damage to equipment if disregarded.

NOTE: A NOTE provides additional information intended to avoid inconveniences during operation.

Inspection	=	examination of actual condition
Service	=	measures to maintain specified condition
Repair	=	measures to restore specified condition
Maintenance	=	inspection, service, and repair, where necessary
Preventive Maintenance	=	Maintenance measures at regular intervals

Typing conventions in this manual

Controls ("hard" keys and screen keys / fields / knobs) are designated as »**Control Name**«, e.g.

»**Configuration**«

Screen pages are indicated as »Screen page«, e.g.

»Alarm limits«

On-screen messages are printed in **bold**, e.g.

SpO_2 measurement is activated.

General WARNINGS and CAUTIONS

WARNING !

Strictly follow Operator's Instruction Manuals

Any use of the product requires full understanding and strict observation of all portions of these instructions as well as the Operating Instructions of the Evita 4 and Evita 2 dura ventilators, respectively. The equipment is only to be used for the purpose specified under "Intended Use" (page 8). Observe all WARNINGS and CAUTIONS as rendered throughout the manuals and on labels on the equipment.

WARNING !

DANGER, risk of explosion if used in the presence of flammable anesthetics.

The equipment is neither approved nor certified for use in areas where combustible or explosive gas mixtures with air or with nitrous oxide are likely.

WARNING !

Electrical connections to equipment which is not listed in these Operating Instructions should only be made following consultations with the respective manufacturers or a qualified expert.

CAUTION !

Restriction of Distribution

Federal Law and Regulations in the United States and Canada restrict this device to sale by or on the order of a physician.

CAUTION !

Traceability

Federal Law in the United States requires traceability of this equipment. Please return the self addressed registration card included with the product and fill in the required information.

CAUTION !

Accessories

Use only accessories listed in the Ordering Information (page 26).

Precautions During Preparation

WARNING !

Installation of the Evita 4 Sat Option may be performed by factory trained and authorized service personnel only.

WARNING !

Only use Nellcor OXISENSORS™.

Observe all Instructions for Use of the sensors. Incorrect positioning or use can cause tissue damage.

Precautions During Operation

WARNING !

Never use sensors with damaged, exposed electric wires.

Risk of electric shock.

WARNING !

Keep cleaning fluid away from patient's eyes. It will cause eye irritation. In case of contact wash out with water immediately.

Precautions During Maintenance

WARNING !

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

WARNING !

Preventive Maintenance work on the Evita 4 and Evita 2 dura ventilators and their components may be performed by trained and factory authorized staff only.

WARNING !

Never operate a ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to properly trained and factory authorized service personnel.

CAUTION !

Maintenance

In case of malfunction of this component, contact your local DraegerService or our Factory Authorized Technical Service Center.

The devices must be inspected and serviced (preventive maintenance) by competent and factory authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.

Maintenance or repair of Evita ventilators shall be performed only by Draeger authorized technical service representatives.

Intended Use

Evita 4 Sat – optional SpO_2 monitoring for intensive care ventilators Evita 4 or Evita 2 dura.

- For non-invasive measurement of functional oxygen saturation in a patient's arterial blood.
- For measuring patient pulse rate.
- For monitoring functional oxygen saturation with upper and lower alarm limits.
- For monitoring pulse rate with upper and lower alarm limits.

Preparation

Installation

WARNING !

Installation of the Evita 4 Sat option may be performed by factory trained and authorized service personnel only.

Sensor Selection

WARNING !

Only use Nellcor OXISENSORS™.

Observe all Instructions for Use of the sensors. Incorrect positioning or use can cause tissue damage.

The table below is an aid to sensor selection, describing the specific sensors available together with their characteristics.

Sensor type	OXISENSOR™ D-20	DURASENSOR™ DS-100 A	OXISENSOR™ I-20	OXISENSOR™ R-15	OXISENSOR™ R-15
Age group	Children	Adults	Infants	Adults	Adults
Patient weight	10 to 50 kg	>40 kg	3 to 20 kg	>50 kg	>30 kg
Period of use	Short and long-term monitoring	Short-term monitoring	Short and long-term monitoring	Short and long-term monitoring	Short and long-term monitoring
Patient mobility	Limited activity	Inactive patients only	Limited activity	Inactive patients only	Inactive patients only
Preferred measuring point	Finger	Finger	Toe	Nose	Finger
Sterility[1)]	Sterile-packaging	———	Sterile-packaging	Sterile-packaging	———

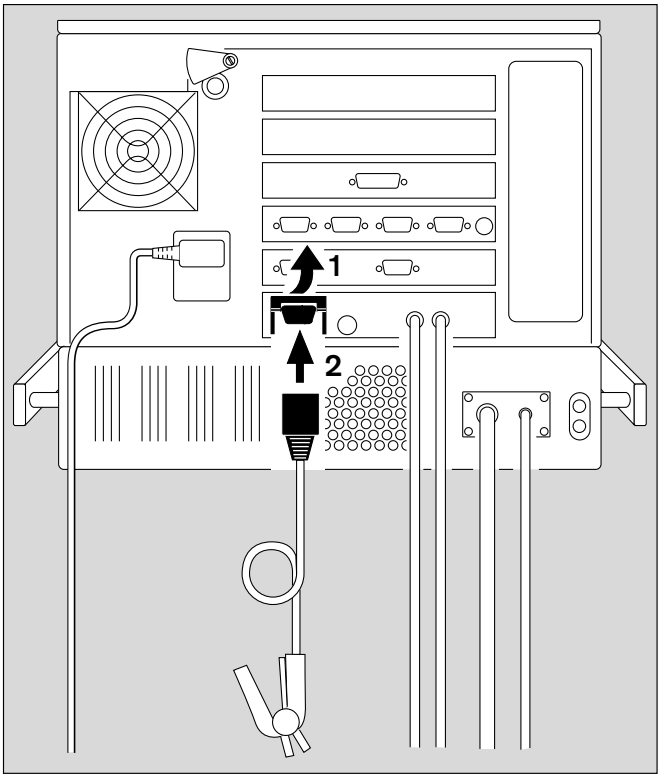
1) in undamaged, unopened packaging

- Select the appropriate sensor.

1 Raise socket cover flap on the back of the ventilator.

2 Insert sensor plug.

NOTE: Use sensor extension cable (part no. 82 01 015) if necessary



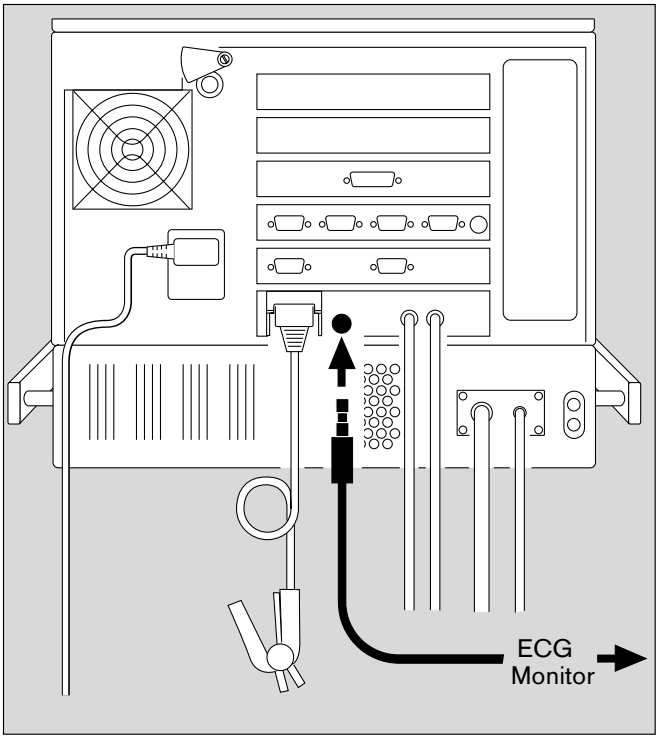
C-lock ECG Synchronization

In the event of considerable patient movement, or if the patient's arterial circulation is very low, SpO_2 measurement signals can be improved with C-Lock ECG synchronization. In this case, the ventilator receives two separate signals regarding heart activity:

– an optical signal from the SpO_2 sensor
and
– an electrical signal from the ECG monitor.

Evita 4 and Evita 2 dura use the R-wave of the ECG signal to detect patient pulse and to synchronize with the SpO_2 measurement.

- Connect ECG signal from the ECG monitor to the back of the ventilator with cable and jack.
  See "Technical Data" on page 23 for requirements regarding input signal specifications and connector pin Layout.



In the event of a delayed ECG signal

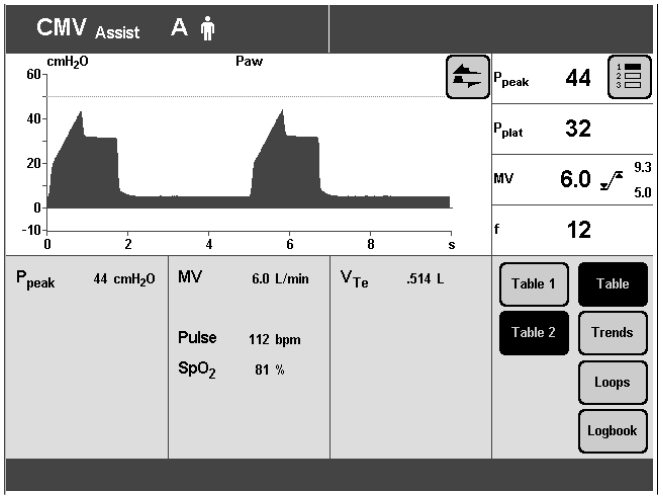
If the SpO2 signal is more than 40 milliseconds delayed with respect to the QRS complex of the ECG signal, synchronization may be adversaly affected.
If there is any suspicion of a problem of this type, use the Evita 4 / Evita 2 dura without C-Lock ECG synchronization.

Operation With Evita 4

Measuring SpO2

- Press **»Measured Values«** key.
- Touch **»Table 2«** screen key.

The measured values for SpO2 and pulse rate are displayed in Table 2 of the »Measured Values« screen page.

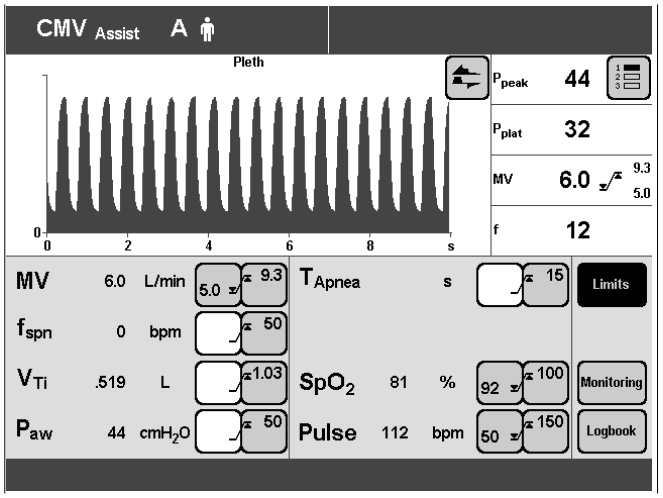


Displaying the Plethysmogram

Available in all screen pages.
If the »Pleth« waveform is not yet displayed on the screen.

- Touch » « screen key and
- touch **»Pleth«** screen key.

Example:



NOTE: If you wish to display the plethysmogram permanently in the standard screen page, please refer to Evita 4 Operating Instructions: Configuration ->Screen -> SelectingWaveforms

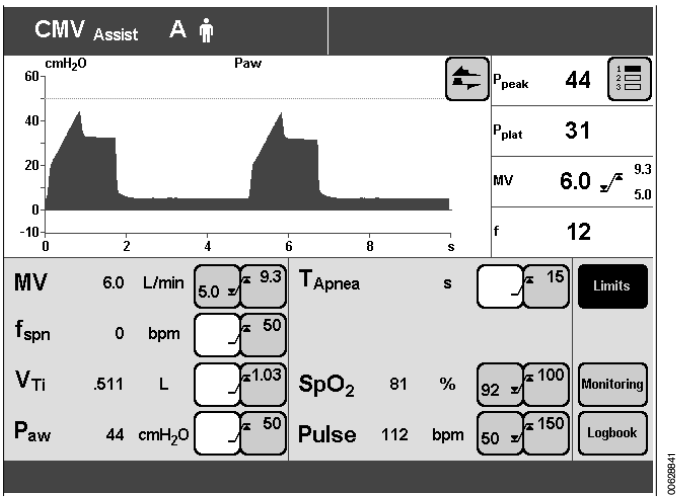
Setting Alarm Limits

- Press **»Alarm limits«** key.
- Note software version of unit.

Units with software version 3.n or lower:

The **»Alarm limits«** screen page is displayed (example) for units with software version 3.n or lower: All adjustable alarm limits are displayed on this page.

↓ = lower alarm limit
↑ = upper alarm limit

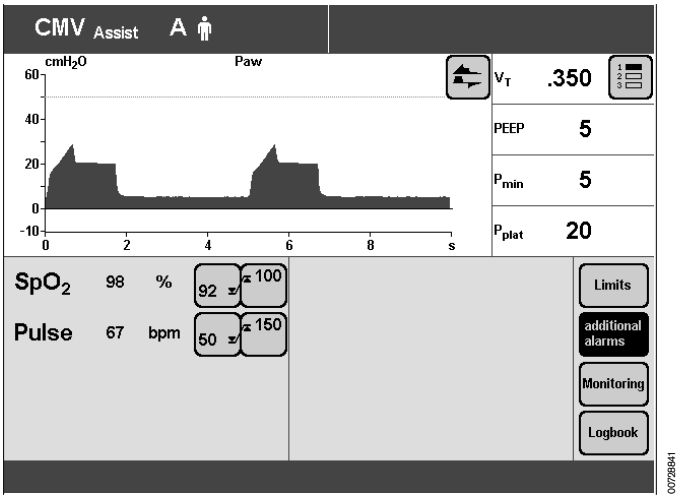


Units with software version 4.n or higher:

- Touch **»additional alarms«** screen key.

The **»additional alarms«** screen page is displayed (example) for units with software version 4.n or higher:

The alarm limits for SpO2 and pulse rate are displayed on this page.



Example:

To set lower alarm limit for pulse rate:

- Touch »↓ « screen key for the pulse rate lower alarm limit: it will change color from green to yellow.
- Set alarm limit with the dial knob and press to confirm. The new alarm limit will now be in effect.

Switching off SpO_2 Monitoring

- Press »**Alarm limits**« key.
- Touch »**Monitoring**« screen key.
- Touch »**SpO_2**« screen key.
- Press the dial knob to switch off SpO_2 monitoring.

Configuring Start Up Defaults for Alarm Limits

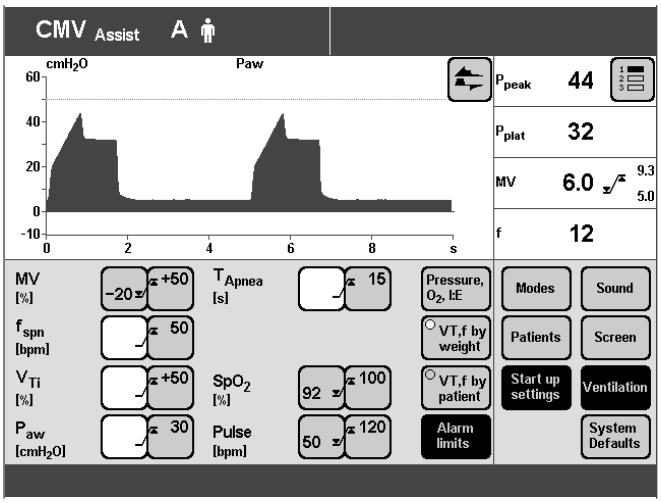
- Press **»Configuration«** key.
- Touch **»Ventilation«** screen key.

Enter access code 3032:

- Touch the respective screen keys.

- Touch **»Start up settings«** screen key.
- Touch **»Alarm limits«** screen key.

Display (example):



Defaults of the SpO_2 and pulse alarm limits:

Measurement parameter	Adjustment range	Factory-set start-up defaults	Hospital-specific defaults
SpO2	51 to 100 % 50 to 99 %	100 % 92 %	....
Pulse	21 to 250 bpm 20 to 249 bpm	150 bpm 50 bpm	....

Any hospital-specific defaults selected for start-up may be entered in the right-hand column of this table.

To modify these default alarm limits:

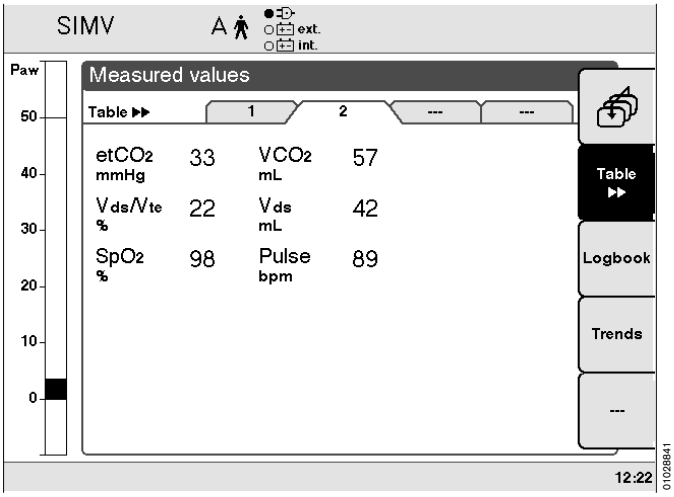
- Touch screen key of the alarm limit to be changed.
- Change value = turn dial knob.
- Confirm value = press dial knob.

Operation With Evita 2 dura

Measuring SpO2

- Press »**Measured Values**« menu key.
- Press »**Table ▶▶**« menu key.

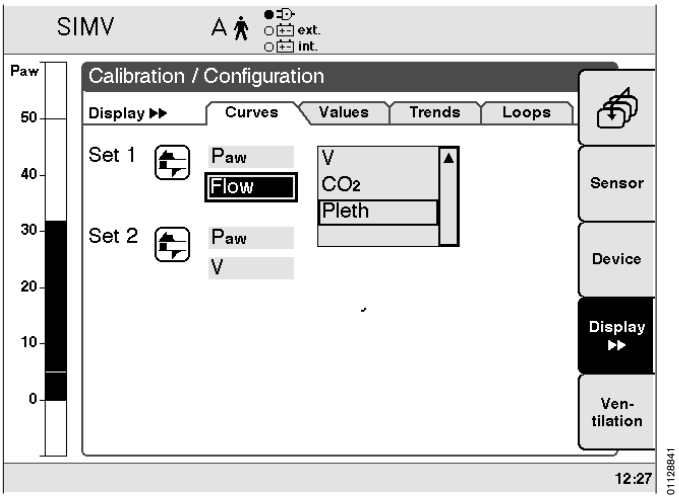
The measured values for SpO2 and pulse rate are displayed in Table 2 of the »**Measured Values**« screen page.



Displaying the Plethysmogram

- Press »**Calib./Config.**« menu key.
- Press »**Display**« menu key.
- By turning and pressing dial knob, select screen position (top or bottom) and in which set of waveforms (Set 1 or Set 2) the plethysmogram is going to be displayed.

  Example: Set 2 and display in top position
- Select top screen field in Set 2 = turn dial knob. Confirm = press dial knob. A list of available selections is displayed on the right side of the screen,
- Select »**Pleth**« = turn dial knob.
- Confirm selection = press dial knob.

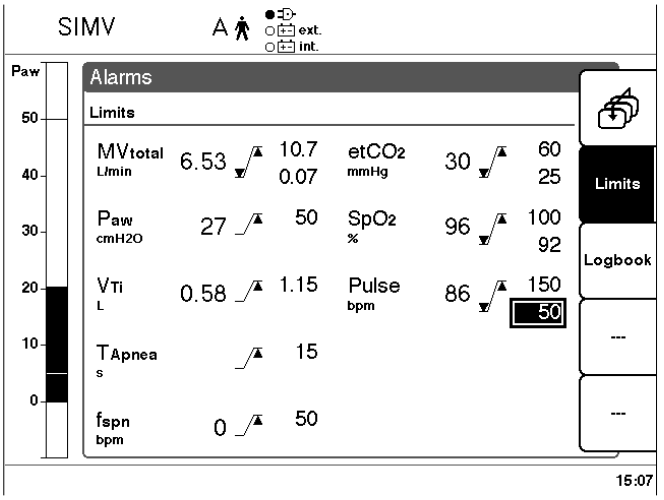


Setting Alarm Limits

- Press **»Alarms«** menu key.
- Press **»Limits«** menu key.

  The »Alarm limits« screen page is displayed (example):
  All adjustable alarm limits are displayed on this page.

  ⌟ = lower alarm limit
  ⌜ = upper alarm limit



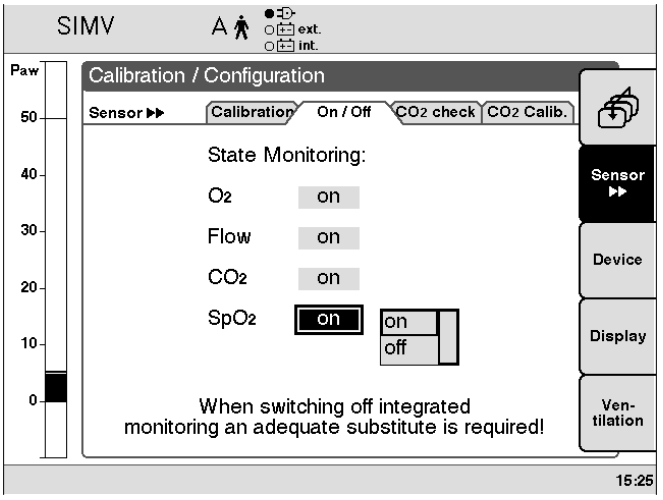
Example:

To set lower alarm limit for pulse rate

- Select screen field with lower alarm limit
  = turn dial knob.
  Confirm = press dial knob.
- Set alarm limit by turning dial knob, press knob to confirm. The new alarm limit will now be in effect.

Switching off SpO2 Monitoring

- Press »**Calib./Config.**« key.
- Select the »**Sensors on/off**« menu with »**Sensors ▶▶**« menu key.
- Select »**SpO2**« screen key = turn dial knob,
- Confirm = press dial knob.
- Switch off SpO2 monitoring = Select »**off**« by turning dial knob, press knob to confirm.



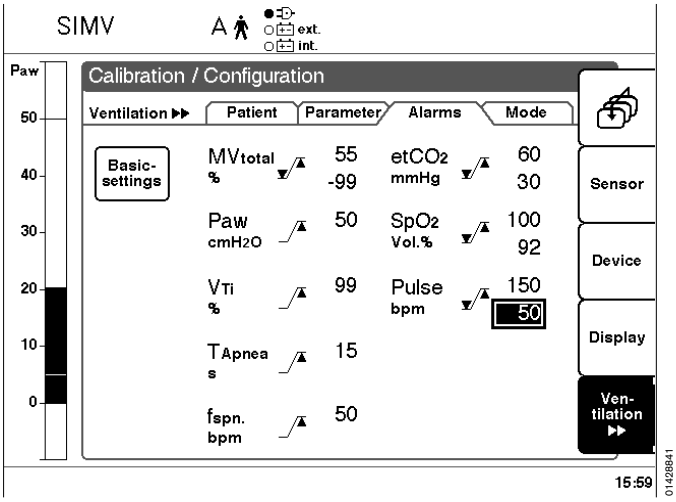
Configuring Start Up Defaults for Alarm Limits

- Press **»Calib./Config.«** menu key.
- Press **»Ventilation«** menu key.

Enter access code 3032:

- Turn and press dial knob in order to enter respective digits one at a time.
- Select »**Alarms**« menu screen by pressing »**Ventilation ▶▶**« twice. »**Alarms**« screen page will appear.

Display (example):



Defaults of the SpO_2 and pulse alarm limits:

Measurement parameter	Adjustment range	Factory-set start-up defaults	Hospital-specific setting
SpO2 ↓/↑	51 to 100 % 50 to 99 %	100 % 92 %	....
Pulse ↓/↑	21 to 250 bpm 20 to 249 bpm	150 bpm 50 bpm	....

Any hospital-specific defaults selected for start-up may be entered in the right-hand column of this table.

To modify start-up defaults of alarm limits (e.g. lower alarm limit for pulse rate):

- Select "Pulse" lower alarm limit = turn dial knob. Confirm selection = press dial knob.
- Change value = turn dial knob.
- Confirm value = press dial knob.

Applying SpO2 Sensors

Tips to Avoid Artifacts

Nellcor compatible sensors must be used exclusively, and they must be correctly positioned to avoid the risk of measuring artifacts and of tissue damage.

WARNING !

Never use sensors with damaged, exposed electric wires.

Risk of electric shock.

Oxiband-OXI-A/N and OXI-P/I adhesive strips must not be reused, because they might not adhere properly.

Do not overstretch adhesive strips.

Never double-up strips, as this may lead to venous pulsation and failure of the pulse signal.

High intrathoracic pressure, pressure on the thorax and other consequential impairments of venous flow can lead to venous pulsation with failure of the pulse signal.

The pulse signal may fail in the presence of shock, low blood pressure, severe vasoconstriction, major anemia, hypothermia, arterial occlusion proximal to the sensor, and asystole.

In the presence of bright light (e.g. from surgical lamps or direct sunlight), the sensor must be covered, otherwise the pulse signal may fail or become inaccurate.

The sensor should not be positioned on extremities together with an arterial catheter, sphygmomanometer cuff or intravascular venous infusion: the pulse signal may fail, and measurement may become inaccurate.

Measurement accuracy may also be impaired in the event of significant concentrations of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin.

Intravascular dyes, such as methylene blue, may also impair measurement accuracy.

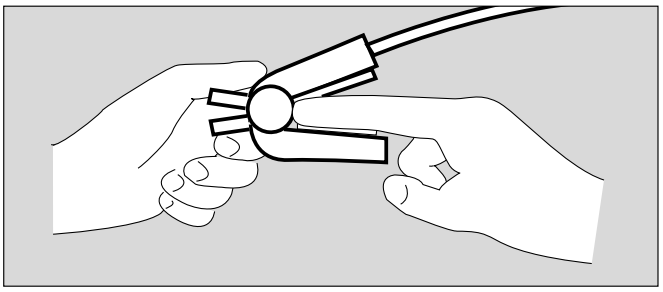
Electrosurgery can impair measuring accuracy; leads and sensor should therefore be positioned as far away as possible from the site of electrosurgery and its neutral electrode.

Sensor performance may be impaired if the patient moves excessively, leading to inaccurate results. In such cases the sensor should be applied to a different location in order to reduce the likelihood of movement artifacts.

Applying the Durasensor DS-100 A

Reusable sensor for short term monitoring of relatively quiet patients weighing over 40 kg.

The sensor is preferably positioned on the index finger, although other fingers may also be used. The little finger should be used if the patient is particularly large or obese.

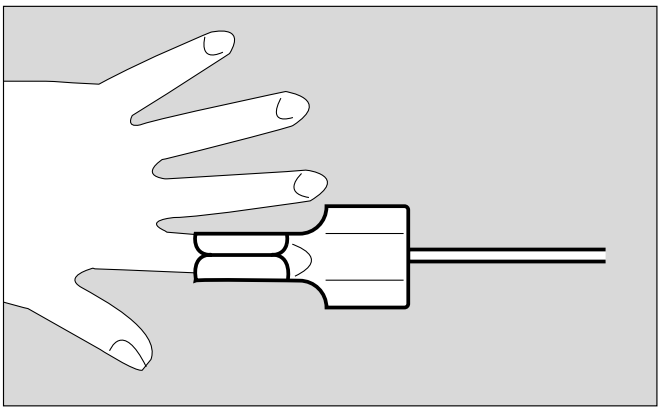


- Open clip slightly and slide sensor onto the finger. The tip of the finger must touch the end, and the soft padding must rest on the nail and tip of the finger. The lead should be on top of the finger.
- Verify that the finger is not compressed or hurt by the clip.
- Change the application site at least every 4 hours in order to avoid impairing blood circulation.

Applying the Oxisensor D-25 and D-20

Adhesive sensors for short and long-term monitoring of patients with limited mobility weighing from 15 to more than 50 kg.

Long fingernails make application of the sensor more difficult, and colored nail varnish impairs accuracy of measurement.

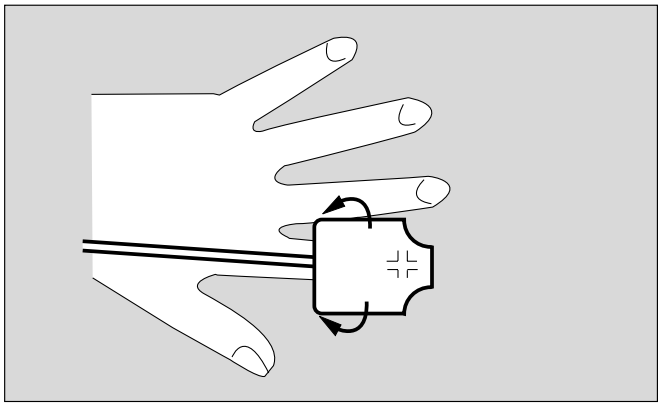


- Cut fingernail if necessary.
- Remove nail varnish if necessary.

Then:

- Remove protective film from adhesive strip.
- Place sensor on a flat surface with adhesive side facing upwards.
- Center tip of patient's index finger onto optical element located opposite the cable end. Wrap adhesive strips around finger.
- Fold the cable end of the sensor over the tip of the finger, and position so that the markings on both sides line up correctly. Press sensor gently into place and wrap remaining adhesive strips around the finger.

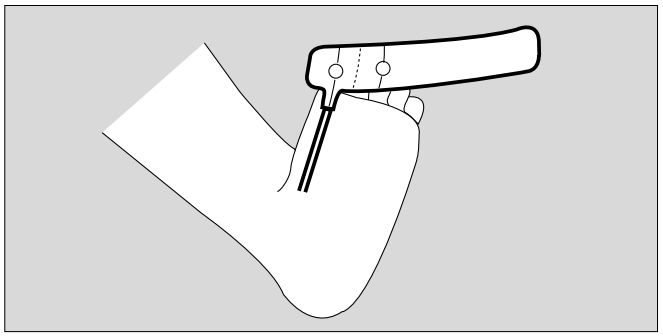
  A thinner finger should be used instead of the index finger if the patient is very obese.



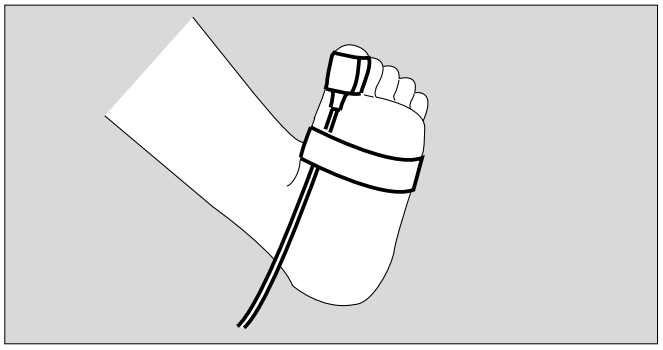
Applying the Oxisensor I-20

Adhesive sensor for short and long-term monitoring of patients with limited mobility and weighing between 3 and 15 kg.

- Remove protective film from adhesive strip.



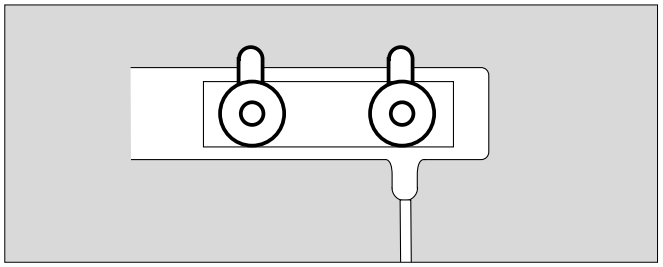
- Place sensor underneath the big toe, so that the dotted line is on the inner edge of the toe and the marking is positioned on the middle of the toe.
- Wrap sensor strip around the toe so that the other marking is exactly on top of the toenail.
- Secure sensor cable to the foot with the additional adhesive tape provided.



Reusing the sensor

The sensor can be reused if the tape is still sticky. Adhesion is improved by small additional adhesive spots.

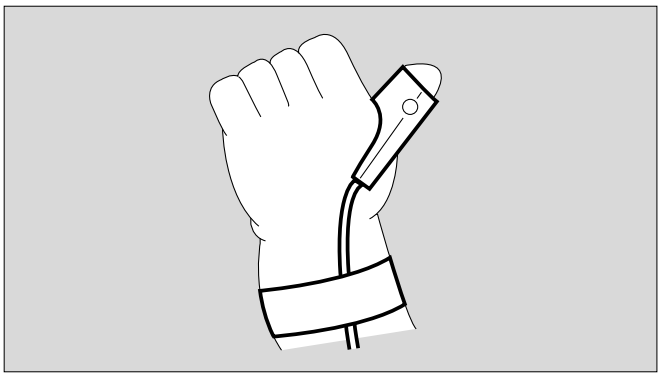
- Hold adhesive spots by their blue tabs, peel them off the backing paper and remove protective film.
- Affix one spot concentrically to each optical element.
- Position sensor as described above.



Other measuring point

The sensor is preferably applied to the big toe because the toe moves less than a patient's hand. If the big toe cannot be used, however, the sensor may also be applied to the thumb.

- Peel protective film off adhesive strip.
- Position the sensor under the thumb so that the dotted line is on the inner edge of the thumb and the marking is positioned on the middle of the thumb.
- Wrap the sensor round the thumb so that the other marking is exactly on top of the thumbnail.
- Secure sensor cable to the hand with the additional adhesive tape provided.



Applying the Oxisensor R-15

Disposable adhesive sensor for short and long-term monitoring of **immobile** patients weighing more than 50 kg. Preferably used for patients likely to be suffering from severe vasoconstriction or poor circulation.

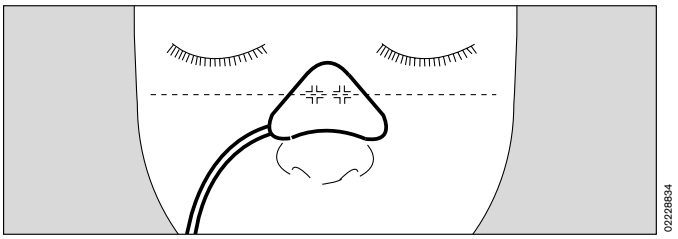
- Clean bridge of patient's nose with cleaning fluid in enclosed ampule.

WARNING !

Keep cleaning fluid away from patient's eyes. It will cause eye irritation. In case of contact wash out with water immediately.

- Peel off the protective backing

- Align sensor symmetrically on the bridge of the nose: the two symbols should be placed on the bone/ cartilage boundary.



- Press sensor gently into place and hold for 10 seconds to ensure good adhesion.

NOTE: The R-15 sensor may not be used on patients with nasal intubation or a mask.

Troubleshooting

Alarm messages in the alarm display field are displayed in hierarchical order.
If, for example, two faults are detected at the same time, the more urgent of the two is displayed.

The priority for alarm messages is indicated by exclamation marks:
Warning = Message with top priority **!!!**
Caution = Message with medium priority **!!**
Advisory = Message with low priority **!**

In the table below, the messages are listed in alphabetical order.
The table should help you to identify the cause of an alarm and to ensure rapid remedy of the problem.

Message		Cause	Remedy
No Pulse	**!!!**	SpO_2 sensor detached	Check SpO_2 sensor attachment
Pulse high	**!!!**	Pulse rate exceeds upper alarm limit.	Check patient condition. Check ventilation pattern. If necessary, adjust alarm limit.
Pulse low	**!!!**	Pulse rate below lower alarm limit.	Check patient condition. Check ventilation pattern. If necessary, adjust alarm limit.
SpO2 high	**!!!**	SpO_2 exceeds upper alarm limit.	Check patient condition. Check ventilation pattern. If necessary, adjust alarm limit.
SpO2 low	**!!!**	SpO_2 below lower alarm limit.	Check patient condition. Check ventilation pattern. If necessary, adjust alarm limit.
SpO2 measurement inop	**!!!**	SpO_2 sensor defective.	Replace sensor.
		SpO_2 measurement defective.	Call DraegerService.
SpO2 sensor	**!!!**	The plug of the SpO_2 sensor was disconnected during operation.	Reconnect the sensor plug. Test.
		Sensor defective.	Use new sensor.

Maintenance

CAUTION !

Maintenance

In case of malfunction of this component, contact your local DraegerService or our Factory Authorized Technical Service Center.

The devices must be inspected and serviced (preventive maintenance) by competent and factory authorized technical service representatives at regular 6 month intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract through your vendor.

Maintenance or repair of Evita ventilators shall be performed only by Draeger authorized technical service representatives.

WARNING !

To avoid any risk of infection, clean and disinfect ventilator and accessories before any maintenance according to established hospital procedures - this applies also when returning ventilators or parts for repair.

WARNING !

Preventive Maintenance work on the Evita 4 and Evita 2 dura ventilators and their components may be performed by trained and factory authorized staff only.

WARNING !

Never operate a ventilator if it has suffered physical damage or does not seem to operate properly. In this case always refer servicing to properly trained and factory authorized service personnel.

Maintenance Intervals

Preventive maintenance	Every 6 months by trained and factory authorized service personnel.

The Evita 4 Sat option is serviced as part of the scheduled preventive maintenance of the Evita 4 and Evita 2 dura ventilators every six months.

Technical Data

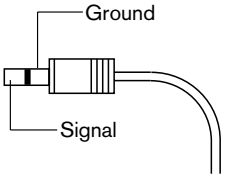
Ambient conditions

During operation	
Temperature	10 to 40 °C (50 to 104 °F)
Atmospheric pressure	700 to 1060 hPa
Rel. humidity	0 to 90 %
During storage and transport	
Temperature	–20 to 60 °C (-4 to 140 °F)
Atmospheric pressure	500 to 1060 hPa
Rel. humidity	0 to 100 %

SpO_2 measurement

Display range	0 to 100 % SpO_2
Accuracy (adults)	
range 70 to 100 % SpO_2	better than ±2 % SpO_2
range 50 to 70 % SpO_2	better than ±3 % SpO_2
range 0 to 50 % SpO_2	not specified
Accuracy (neonates)	
in the 70 to 95 % SpO_2 range	better than ±3 % SpO_2
in the 0 to 70 % SpO_2 range	not specified
in the 95 to 100 % SpO_2 range	not specified
Pulse rate	20 to 250/min
Accuracy	±2/min
Sensors	
Type	Nellcor compatible sensors Oxisensor, Oxiband and Durasensor
Wavelengths	660 nm (red), 920 nm (infrared)

C-Lock ECG Synchronization

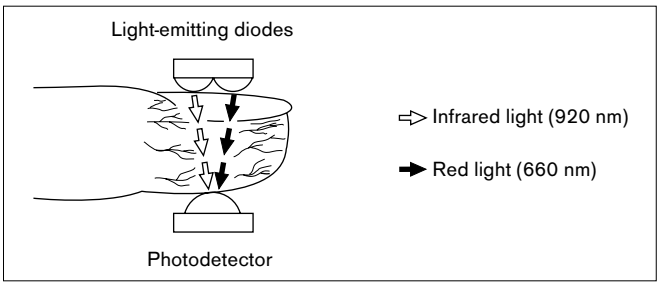
Prerequisite for ECG synchronization signal	pos. pulse with voltage >4.5 V, >10 ms for driving 2 mA.
Max. permissible delay of the signal with reference to the current QRS complex	40 ms
Socket for 2-pole 3.5 mm barrel connector Jack contact assignment	
Signal isolation from other electronic components Dielectric strength	4 kV

Theory of Operation

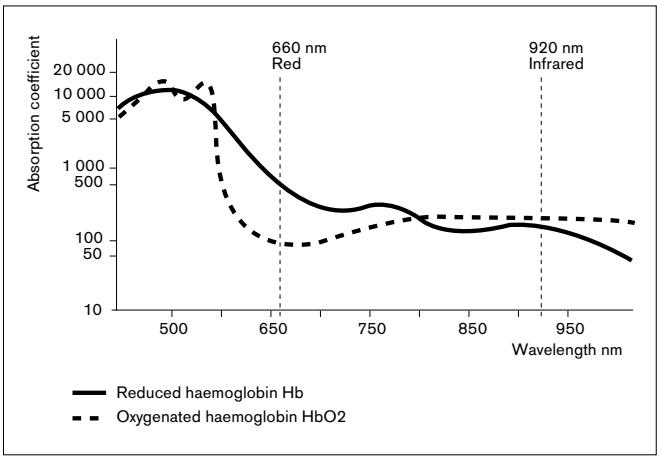
SpO2 Measurement – Measuring Principle

Oxygenated, arterial blood (oxyhemoglobin, HbO_2) has light absorption properties different from unsaturated, venous blood (reduced hemoglobin, Hb). "O_2 saturation" is a logarithmic function of light intensity absorbed by the blood (Lambert-Beer's law).
The effect of dysfunctional hemoglobins, such as carbon monoxide hemoglobin (HbCO) and methemoglobin (MetHb), is negligible under normal circumstances.

The sensor consists of two light-emitting diodes which alternately emit infrared light with typical wavelengths of 920 nm and 660 nm, respectively.
A photodetector placed opposite the LEDs measures the intensity of radiation. The sensor is attached to a part of the body where arterial blood vessels can be transluminated, e.g. finger, toe, bridge of the nose.



These two wavelengths (920 nm and 660 nm) have been chosen because, even in the presence of slight perfusion, they still provide meaningful absorption values for both oxygenated and reduced blood, while at the same time they differ significantly.

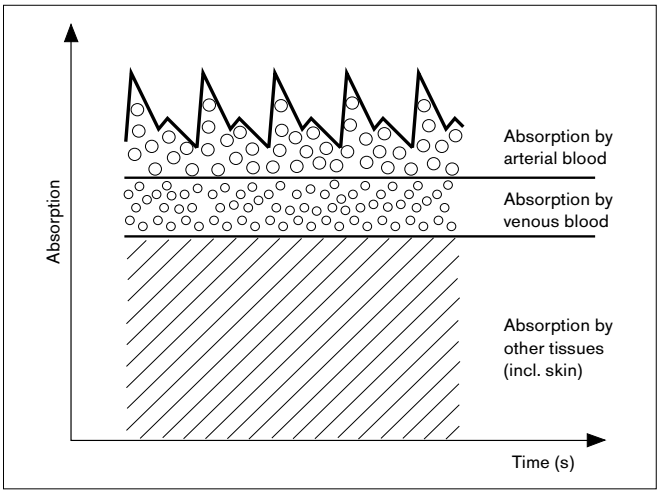


Total absorption of light emitted alternately by the diodes is caused by the pulsating arterial blood, the skin, finger nails, muscular tissue, bones, venous blood.

Except for the pulsating, arterial blood, absorption by all the other components during a defined period of time remains constant as far as volume and optical density are concerned.

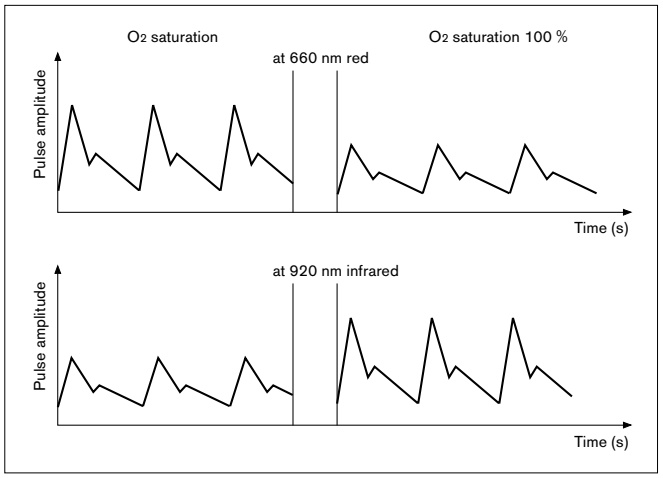
By contrast, the arterial blood pulsating with every heart beat causes a pulse-synchronized volume change in the transluminated tissue, and consequently a pulse-synchronized change of absorption of the light transmitted.

Light absorption is first measured while no pulsating blood is present in the tissue(during diastole). This measurement renders a value for light absorbed by the tissue and by non-pulsating blood.



Normally, this does not change during a pulse phase so it serves as a reference value for the pulsating part of absorption.
The absorption is then measured after the next heart beat, when pulsating blood enters the tissue. During this measurement, light absorption for both wavelengths changes due to the pulsating arterial blood.

The diagram shows an example of the light absorption characteristics of the blood at 660 nm (red) and 920 nm (infrared). With increasing O_2 saturation, the absorption and corresponding pulse amplitude fall at 660 nm but rise at 920 nm. Since the absorption coefficients of HbO_2 and Hb are known for both wavelengths, the system can calculate the quantity of each of these two haemoglobins present in the blood.



The quotient obtained by dividing oxygenated haemoglobin (HbO_2) by the combination of reduced and oxygenated haemoglobin ($Hb+HbO_2$) is termed the "functional saturation":

$$\% \, SpO_2 = 100 \times \frac{HbO_2}{HbO_2 + Hb}$$

This value refers to the hemoglobin which is available to transport oxygen.
The dysfunctional hemoglobins, HbCO and MetHb, can be ignored under normal circumstances, they might, however, impair the accuracy of measurements.

Ordering Information

Item/Description	Part No.
SpO_2 kit (Evita 4 Sat)	84 13 035
consisting of:	
SpO_2 module	86 00 481
Durasensor DS-100 A	82 01 001
Sensor extension cable	82 01 015
Accessories	
Finger sensor Dura DS-100 A	82 01 001
Adhesive sensor D 25 (pack of 24)	82 01 002
Adhesive sensor D 25 (pack of 6)	82 01 035
Adhesive sensor D 25 L (pack of 24)	21 70 175
Adhesive sensor D 20 (pack of 24)	82 01 003
Adhesive sensor D 20 (pack of 6)	82 01 036
Adhesive sensor I 20 (pack of 24)	82 01 004
Adhesive sensor I 20 (pack of 6)	82 01 037
Adhesive sensor R 15 (pack of 12)	82 01 006
Adhesive sensor R 15 (pack of 6)	82 01 039
OXIBAND adhesive sensor, compl.	82 01 013
OXIBAND adhesive strip (pack of 50)	82 01 012
Sensor extension cable	82 01 015

Index

Advisory....6
Alarm.... 21
Alarm limits....12, 15
Artifacts....17

Caution....6
C-Lock ECG Synchronization....10

Default, alarms at start-up.... 12, 15
Durasensor DS-100 A.... 19

Intended use....8

Order list....26
Oxisensor D-20.... 19
Oxisensor D-25.... 19
Oxisensor I-20....19
Oxisensor R-15.... 20

Plethysmogram.... 11, 14
Preparation....10

Safety, patient....4
Sensor, selecting.... 9
SpO_2 measurement, activating....9
SpO_2, measuring....11, 14
SpO_2 sensor, applying.... 17

Technical Data.... 23
Theory, of operation....24
Troubleshooting....21

Use, intended.... 8

Warning....6

These Operating Instructions apply only
☐ to **Evita 4** with Serial No.:
☐ to **Evita 2 dura** with Serial No.:

(check applicable)

Without entry of a Serial No. by Draeger these Operating Instructions are provided for general information only and are not intended for use with a specific device.

Draeger Medical, Inc.
3135 Quarry Road
Telford, PA 18969
215-721-5400
FAX 215-723-5935

90 28 841 - GA 5664.504 enUS
© Dräger Medical AG & Co. KGaA
3rd edition - May 2001
Subject to modifications